

§ 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

(a)(1) If any of the information required in § 1.281(a), except the information required in:

- (i) Section 1.281(a)(5)(iii) (quantity),
- (ii) Section 1.281(a)(11) (anticipated arrival information), or
- (iii) Section 1.281(a)(17) (planned shipment information), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart unless the article of food will not be offered for import or imported into the United States.

(2) If any of the information required in § 1.281(b), except the information required in § 1.281(b)(10) (the anticipated date of mailing), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart, unless the article of food will not be offered for import or imported into the United States.

(b) If you submitted the prior notice via the FDA PNSI, you should cancel the prior notice via the FDA PNSI.

(c) If you submitted the prior notice via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP cancel the entry.

CONSEQUENCES

§ 1.283 What happens to food that is imported or offered for import without adequate prior notice?

(a) For each article of food that is imported or offered for import into the United States, except for food arriving by international mail or food carried by or otherwise accompanying an individual, the consequences are:

(1) *Inadequate prior notice*—(i) *No prior notice*. If an article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If an article of food is refused for lack of prior notice, unless U.S. Customs and Border Protection (CBP) concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(ii) *Inaccurate prior notice*. If prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act. If the article of food is refused due to inaccurate prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(iii) *Untimely prior notice*. If prior notice has been submitted and confirmed by FDA for review, but the full time that applies under § 1.279 for prior notice has not elapsed when the article of food arrives, the food is subject to refusal of admission under section 801(m)(1) of the act, unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. If the article of food is refused due to untimely prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(2) *Status and movement of refused food*. (i) An article of food that has been refused under section 801(m)(1) of the act and paragraph (a) of this section shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(ii) Refused food must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at that port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The